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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,009	06/17/2003	Thomas Ferdinand A. Pijls	05032-00029	5778
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28 STATE STR 28th FLOOR		CHORBAJI, MONZER R		
BOSTON, MA	02109-9601		ART UNIT	PAPER NUMBER
			1797	
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			05/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/601,009	PIJLS, THOMAS FERDINAND A.				
Office Action Summary	Examiner	Art Unit				
	MONZER R. CHORBAJI	1797				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
	VIC CET TO EVOIDE AMONTHU	CLOD THIRTY (20) DAVE				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on <u>20 Au</u>	iaust 2007.					
	action is non-final.					
·						
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>25-27,29-38,40-43 and 47-52</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>25-27,29-38,40-43 and 47-52</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examine	r.					
10)⊠ The drawing(s) filed on <u>17 June 2003</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a)⊠ All b)□ Some * c)□ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.						
See the attached detailed Office action for a list of	or the certified copies not receive	u.				
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary	(PTO-413)				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	nte				
Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	5) Notice of Informal P 6) Other:	ателт Арріїсатіоп				

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DETAILED ACTION

This non-final action is in response to the amendment received on 8/20/07

Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 3. Claims 25, 27, 29, 32-37, 40, 47-48, and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisecky et al (U.S.P.N. 4,141,783) in view of Badertscher (GB 2 036 534) and further in view of Fabre (U.S.P.N. 4,689,237).

Regarding claim 25, Pisecky discloses a method for spray drying heat sensitive liquids with steam (col.3, lines 47-56). An example of such a liquid is skimmed milk concentrate where Pisecky describes substantially atomizing the liquid form (col.6, lines 38-40) while admixing steam in a mixing chamber (col.6, lines 30-31). As to the limitation of producing a pasteurized or sterilized product, this subject matter is taught in the Pisecky reference and also as to the limitation that the steam heats the chamber,

one of ordinary skill in the art would recognize that as steam is flown through annular chamber 18, heat from steam is transferred to the walls of the chamber, thereby raising the temperature of the walls of annular chamber 18. Pisecky teaches a liquid steam weight ratio between 1.6-10 (In col.10, Example 1, dividing 600 Kg/h of product into 90 Kg/h of steam is equal to 7). In addition, Pisecky teaches drying the pasteurized liquid into powder form (see examples 1-4). Upon evaluating the disclosure, the "wherein" clause is considered as material not subject to patentability and it does not further limit the scope of claim 25, since it intended result in a method step. In addition, the totality of the disclosure does not provide any criticality to mixing powdered baby formula with water nor does it provide unexpected results. Pisecky fails to teach the following: liquid solid content of at least 53%, steam pressure between 3-20 bar, temperature in the mixing chamber is between about 120°C and 250°C and the liquid residence time in the mixing chamber between 0.2-20 millisecond.

Badertscher teaches a nozzle used in the treatment of food products with steam. Badertscher teaches treating a liquid having a solid content of at least 53% (page 5, left column, 60% solids) and that steam pressure between 3-20 bar (page 4, left column). Furthermore, Badertscher teaches heating concentrated milk in the mixing chamber to a temperature from 70° C and 150° C (Example 4 on page 4), because at such temperature range the heated fluid mass may have a high level of homogeneity on leaving the apparatus without variations in pressure (right column, lines 93-96 of page 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to increase the steam pressure in Pisecky to that of Badertscher for

guaranteeing optimal utilization of steam with remarkable stability conditions for sterilization (Badertscher, page 1, right column, lines 90-101). It also would have been obivous to steam treat liquids with high sold contents as taught by the Badertscher reference (page 5, left column), so that wider range of different liquids with various solid contents can be steam treated as compared to only steam treating liquids with low solid contents. It further have been obvious to further heat concentrated milk in the mixing chamber to a temperature from 70° C and 150° C, because at such temperature range does not deleteriously effect the milk and the heated fluid mass may have a high level of homogeneity on leaving the apparatus without variations in pressure as taught by Badertscher (right column, lines 93-96 of page 1).

Badertscher fails to teach that the liquid residence time in the mixing chamber is between 0.2 msec and 20 msec. Fabre describes thermal treatment (col.3, lines 7-8) of milk (col.8, lines 33-35) by injecting steam into it (for example, see col.4, lines 47-50) where milk is thermally treated at a temperature of 160° C for 60 msec or a temperature of 170° C for 5 msec (col.9, lines 3-5) in order to subject the product to a very intense rise in temperature for a very short time (col.7, lines 24-26). It would have been obvious to one of ordinary skill in the art at the time of the invention to treat the milk for between 0.2 and 20 msec at a temperature between 120C and 250C given the teachings of Fabre. It is desireable to subject the product to a very intense rise in temperature for a very short time as shown by Fabre (col.7, lines 24-26). One of ordinary skill in the art would determine, through routine experimentation, the optimum residence time,

temperature of this treatment as these are clearly result-effective variables given the teaches of Fabre.

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Regarding claims 29, 32, 34, 37, 40, 48, and 50-52, Pisecky discloses the following: milk (figure 1:16) contains proteins or fats, the liquid to steam weight ratio between 1.6-10 (In col.10, Example 1, dividing 600 Kg/h of product into 90 Kg/h of steam is equal to 7), the product milk is a stable emulsion since it is treated with steam over a very short time interval (figure 1:16, 17, and col.3, lines 47-56), pasteurized product leaving the mixing chamber flows into a drying chamber (col.6, lines 38-43) where one of ordinary skill in the art would recognize that drying causes the product to agglomerate to produce a powder, spray dried milk is food for infants (col.6, lines 38-42), parallel flow openings for both of product and steam (figure 2:154, 156, 164, and 165), steam inflow is concentric around product inflow in the mixing chamber (figure 2:154, 156, 164, 165, and 104) and the steam is atomized in the mixing chamber (figure 1:4, and col.6, lines 34-37).

Regarding claim 27, Pisecky fails to teach using steam with pressure values in the range of 5-15 bars. Badertscher teaches using steam with pressure values between 3-20 bar (page 4, left column). It would have been obvious to one of ordinary skill in the art at the time the invention was made to increase steam pressure of Pisecky to that of Badertscher so that optimal utilization of steam with remarkable stability conditions for sterilization (Badertscher, page 1, right column, lines 90-101) can be guaranteed.

Regarding claim 33, Pisecky does not specifically describe heating the product to a temperature from 120°C and 150°C. Badertscher reference teaches (Example 4 on

page 4) heating milk to a temperature from 70° C-150° C. It would have been obvious to one of ordinary skill in the art at the time the invention was made to increase Pisecky's heat treatment temperature for milk as taught by the Badertscher reference sot that effective sterilization of milk is accomplished.

Regarding claims 35-36, both Pisecky and Badertscher fail to teach that milk is injected into a vessel where flash evaporation occurs. Fabre describes how the temperature of milk undergoes an instantaneous rise then the milk is held over a minimum time interval to achieve destruction of germs and afterwards the holding time interval ends in flash evaporation in order to reduce the temperature of the heated milk before it enters the final cooling stage (col.8, lines 42-49). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the modified method in Pisecky/Badertscher with the flash evaporation step in order to reduce the temperature of the heated milk before it enters the final cooling stage as explained by Fabre (col.8, lines 42-49).

Regarding claim 47, Pisecky discloses various mass flow rates for steam and milk through examples 2-4 in columns 10-11. In example 2, the ratio of the mass flow rates of the milk concentrate to steam is 6.7, or in example 3 where the mass ratio is 10 or in example 4, the mass ratio is 11.6. Furthermore, Pisecky describes that steam is supplied at a rate to achieve the desired temperature of the liquid (col.3, lines 47-56). One of ordinary skill in the art would recognize that each liquid product would have a different thermal treatment temperature that is related to the amount of steam injected such that changing the mass ratio of the liquid product to the injected steam is a matter

of routine experimentation as evidenced by the various ratio of mass flow rates shown in Pisecky.

4. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pisecky et al (U.S.P.N. 4,141,783) in view of Badertscher (GB 2 036 534) and Fabre (U.S.P.N. 4,689,237) as applied to claim 25 and further in view of Den Hollander (U.S.P.N. 5,558,819).

Pisecky, Badertscher, and Fabre fail to teach placing a distribution plate into the steam inflow openings. Den Hollander place distribution plates into steam inflow openings (figure 2:52). It would have been obvious to one having ordinary skill in the art at the time the invention was made to place a distribution plate into steam inflow opening of the spray drying atomizer wheel of the modified method in Pisecky/Badertscher/Fabre as taught by Den Hollander, since distribution plates ensure steam uniform distribution (Den Hollander, col.3, lines 40-43).

5. Claims 26 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisecky et al (U.S.P.N. 4,141,783) in view of Badertscher (GB 2 036 534) and Fabre (U.S.P.N. 4,689,237) as applied to claim 25 and further in view of Rubens (EP 0 438 783).

Regarding claims 26 and 30-31, Pisecky, Badertscher, and Fabre fail to disclose specification values for the size of the mixing chamber and for the outlet opening.

Rubens discloses a size for the mixing chamber (page 5, numbered lines 4-7) and for the outlet opening between 6.3 mm to 13 mm (page 5, numbered lines 32-35) and further teaches that the value for the opening can be made smaller depending on other

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variables, i.e., temperature, such that modifying the diameter of the outlet opening is a matter of choice of design that depends on the type of operational model used (page 5, numbered lines 33-35). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified method in Pisecky/Badertscher/Fabre by modifying the sizes of the mixing chamber and the outlet openings as taught by Rubens since such modifications depend on the temperature and moisture content desired as well as the flow rates of the heating medium for heat treating liquid products (page 5, numbered lines 6-7 and lines 33-34).

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6. Claims 38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisecky et al (U.S.P.N. 4,141,783) in view of Badertscher (GB 2 036 534) and Fabre (U.S.P.N. 4,689,237) as applied to claims 37, 40 and further in view of Passey (U.S.P.N. 3,564,723).

Regarding claim 38, Pisecky, Badertscher, and Fabre fail to teach recirculating steam. Passey uses superheated steam to pasteurize milk (col.1, lines 17-21, lines 64-66, and col.2, lines 1-2) where steam is bled off the drying chamber to be superheated and then is returned back to the drying chamber (col.2, lines 21-27), because little energy is required to reheat an amount of superheated vapor as compared to the energy required to resuperheat the same amount of vapor resulting in a highly efficient process (col.2, lines 48-51). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the modified method in Pisecky/Badertscher/Fabre with the steam recirculation step, because little energy is required to reheat an amount of superheated vapor as compared to the energy required

to resuperheat the same amount of vapor resulting in a highly efficient process as shown by Passey (col.2, lines 48-51).

Regarding claim 41, Pisecky uses two nozzles (figure 2:164 and 165), wherein the outflow openings of the nozzles (unlabeled output of each nozzle in figure 2) are arranged such that outgoing sprays includes product and steam, contacting each other (col.8, lines 30-33 and lines 39-41).

7. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pisecky et al (U.S.P.N. 4,141,783) in view of Badertscher (GB 2 036 534), Fabre (U.S.P.N. 4,689,237) and Passey (U.S.P.N. 3,564,723) as applied to claim 41 and further in view of Hovmand et al (U.S.P.N. 4,062,641).

Pisecky, Badertscher, Fabre, and Passey fail to teach recirculating non-agglomerated particles to the drying chamber through spray nozzles. Hovmand teaches applying sequential heating steps by recirculating the non-agglomerated particles (col.1, lines 47-53). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified method in

Pisecky/Badertscher/Fabre/Passey by including recirculating means for non-agglomerated particles as taught by Hovmand since a certain degree of agglomeration is desired for good dispersibility of food products in water and milk (col.6, lines 36-38).

8. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pisecky et al (U.S.P.N. 4,141,783) in view of Badertscher (GB 2 036 534) and Fabre (U.S.P.N. 4,689,237) as applied to claim 25 and further in view of Johnston (U.S.P.N. 2,401,077).

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Pisecky, Badertscher, and Fabre do not specifically teach achieving microorganism decimal reduction of at least 2. Johnston teaches achieving decimal reduction of at least 2 (page 3, right column, lines 24-29). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified method in Pisecky/Badertscher/Fabre by including a decimal reduction step as taught by Johnston so that complete spores and bacterial destruction is accomplished (Johnston, page 3, right column, lines 26-28).

Remarks

9. This action is made non-final in order to address limitations in dependent claims that have previously been presented.

Response to Amendment

10. The declaration under 37 CFR 1.132 filed on 08/20/2007 is insufficient to overcome the rejection of claims 25-27, 29-38, 40-43, and 47-52 based upon the obviousness rejection of Pisecky et al in view of Badertscher and Den Hollander as set forth in the last Office action because: declarant has provided opinion evidence on the legal conclusion at issue, instead of factual evidence supporting his position on the issue of residence time. More specifically, the issue of residence time in light of the Den Hollander teachings.

Response to Arguments

11. Applicant's arguments with respect to claims 25-27, 29-38, 40-43, and 47-52 have been considered but are moot in view of the new ground(s) of rejection.

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On pages 9-11 of the Remarks section, Applicant argues that Pisecky fails to teach atomizing the product in liquid form while admixing with steam in a mixing chamber heated by the steam and that Pisecky is silent with regard to pasteurization or sterilization.

Pisecky discloses a method for spray drying heat sensitive liquids with steam where an example of such a liquid is skimmed milk concentrate. Further, Pisecky describes substantially atomizing the liquid form (col.6, lines 38-40) while admixing steam in a mixing chamber (col.6, lines 30-31). As to the limitation of producing a pasteurized or sterilized product, this is an inherent subject matter of the Pisecky reference. Also, as to the limitation that the steam heats the chamber, one of ordinary skill in the art would recognize that as steam is flown through annular chamber 18, heat from steam is transferred t the walls of the chamber, thereby raising the temperature of the walls of the annular chamber 18.

On page 13 of the Remarks section, Applicant argues that Rubens method intentionally heat-damages food products while the instant claims avoid this result.

Ruben is combined with Pisecky, Badertscher, and Fabre for disclosing specific values for the size of the mixing chamber and for the outlet opening. Specifically, Rubens teaches that, for example, the value for the opening can be made smaller depending on other variables such as temperature. As such modifying the diameter of the outlet opening is a matter of design that depends on the type of operational model used (page 5, numbered lines 33-35). Ruben uses steam for heat-treatment of food products and the combination has nothing to do with his intended use of the method.

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Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571)272-1271. The examiner can normally be reached on M-F 9:00-5:30.

- **13.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
- 14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill Warden/ Supervisory Patent Examiner, Art Unit 1797

/M. R. C./